

REMARKS

This responds to the Office Action dated 22 February 2011. Claims 1-41 are pending in the application. Claims 31-37 have been withdrawn. Claims 1, 12, 20 and 28 are amended. Support for the amendments is provided by at least FIGS. 3 and 6 and the description at page 7 of the present application. No new matter has been added.

Claim Rejections – 35 U.S.C. §103

Claims 1-30 and 38-41 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,545,178 to Kensey et al. in view of U.S. Published Application No. 2002/0183787 to Wahr et al. and U.S. Published Application No. 2003/0176890 to Buckman et al. Applicant respectfully traverses this rejection.

Claim 1 as amended recites, “the ratchet mechanism including a first member that maintains a fixed position relative to the filament and terminates proximal of a distal end of the filament.” Claim 12 as amended recites, “wherein the filament provides a pivotal connection of the internal component to the first member distally of the ratchet mechanism.” Claim 20 as amended recites, “wherein the filament provides a pivotal connection of the anchor to the first member distally of the ratchet mechanism.” Claim 28 as amended recites, “wherein the strap and locking hub are separate from the filament, anchor and sealing plug and are positioned proximal of the anchor and a distal end of the filament.”

Kensey discloses with reference to FIGS. 1-5 a device 20 used to close and seal a tissue puncture. The device 20 includes a sealing member 36, an anchoring member 38, a holding member 40, and a positioning filament 42 that interconnects the features 36, 38,

40. The holding member 40 is constructed as a disc that slides along the filament 42 to compress the sealing member 36 toward the anchoring member 38 (*see* FIGS. 6 and 7). The holding member 40 is held in place after compressing the sealing member 36 by positioning a knot in one strand of the filament 42 on a proximal side of the holding member 40 and tying off the opposite strand of the filament 42 outside of the tissue layer (*see* FIG. 5 of Kensey). The holding member 40 is a single-piece device that is void of a ratchet mechanism. Furthermore, the holding member 40 moves in its entirety toward the anchor along the filament 42 to compress the sealing member 36. The holding member 40 is always positioned proximal of the sealing member 36 and does not at any time pass through any portion of the sealing member 36. There is no disclosure or suggestion by Kensey of combining the holding member 40 with any other feature to assist in compressing the sealing member 36 or maintaining the sealing member 36 in a compressed state. Further, there is no disclosure or suggestion by Kensey of connecting the anchoring member 38, sealing member 36 and holding member 40 together with anything but the filament 42.

Wahr discloses with reference to FIGS. 1 and 11 a closure device 10 that includes an anchor 12 directly connected to a tether 16. The tether 16 extends through and connects to a second anchor 14 via a releasable fixation mechanism 30 that is carried by the second anchor 14 and directly contacts the tether 16. When released, the releasable fixation mechanism 30 permits the second anchor 14 to move along the tether 16 relative to the first anchor 12. When locked, the releasable fixation member 30 fixes a position of the second anchor 14 relative to the first anchor 12.

The Wahr apparatus fails to disclose separate features of a filament, an anchor, a sealing plug, and a two-piece locking apparatus as set forth in each of independent claims 1, 12, 20 and 28. Wahr fails to disclose at least a sealing plug and filament that are separate from the anchors 12, 14 and the fixation member 30. There is no need for a separate filament since the tether 16 is directly connected to the anchor 12. Further, the anchors 12, 14 are intended to directly contact tissue surfaces on opposite sides of a tissue opening to assist in holding a septum primum (SP) against a septum secundum (SS) (*see* FIGS. 9-10). There is no disclosure or suggestion by Wahr to use the closure device 10 to compress a sealing plug. Wahr fails to disclose or suggest providing a pivotal connection of the anchor 12 to a ratchet mechanism with a filament. Wahr fails to disclose or suggest a ratchet mechanism that terminates proximal of a distal end of a filament. As noted by the Examiner, Wahr also fails to disclose any kind of specific ratchet structure, but instead only generally suggests a ratchet mechanism.

Buckman fails to remedy the deficiencies of Wahr and Kensey as they relate to claims 1, 12, 20 and 28. Buckman discloses a ratchet device that includes a bolt 10 having a plurality of serrations 20 along at least one of its ends 18, and a pressure plate 26 with ratcheting lock 28 that ratchets along the serrations 20. There is no disclosure or suggestion by Buckman of using a ratchet mechanism in combination with a filament, anchor, sealing plug, or two-piece locking apparatus. Thus, Buckman suffers from the same deficiencies as Wahr and Kensey as they relate to independent claims 1, 12, 20 and 28.

Both Wahr and Buckman fail to disclose or suggest a separate component from the tether 16 and bolt 10, respectively, for operation of a ratchet feature. The Examiner contends that “one skilled in the art would have a choice between providing a separate ratchet strap (similar to the strap disclosed in Buckman) along a portion of the filament 42, or alternatively, to integrally form ratchet teeth along the filament 42 itself so as to form a ratchet strap that is integral with the filament 42” of the Kensey device. Applicant respectfully disagrees.

First, there would be no motivation for one of skill in the art to form ratchet teeth in the filament 42 of Kensey because such a modification, assuming *arguendo* it were possible, would cause significant structural degradation to the filament 42, and because a filament by its very structure is akin to a piece of thread that is intended to slide through the sealing plug 36 and anchor 38 (and holding member 40), which sliding function would be hindered if the filament 42 included ratchet features.

Further, in order to modify Kensey, one of skill in the art would have to replace the two strands of filament 42 and the holding member 40 with one of the ratchet devices disclosed by Wahr or Buckman. Attaching the anchor to a ratchet mechanism with a filament as set forth in the claims rather than with a strap or bolt as disclosed in Wahr and Buckman has certain advantages. At least FIGS. 1B and 2 of the present application illustrate how the anchor 108 is able to pivotally rotate into different positions during operation of the device due in large part to the filament connection. The anchor 108, if attached directly to the strap and bolt structures disclosed by Wahr and Buckman, would have significantly limited movement, in particular into the position required for delivery

into a vessel as shown in FIG. 1B. The combination of a filament with a locking apparatus having first and second members as set forth in claims 1, 12, 20 and 28, and a filament that provides a pivotal attachment of an anchor to a locking apparatus is novel and distinguishes the claimed invention from the art of record.

Furthermore, the combination of Kensey, Wahr and Buckman fails to disclose or suggest a filament that is separate from a ratchet mechanism and connects the anchor to the locking apparatus such that a ratchet mechanism of the locking apparatus “terminates proximal of a distal end of the filament,” as required by claims 1 and 28.

Thus, Applicant submits that Kensey, Wahr and Buckman fail to disclose or suggest every limitation of claims 1, 12, 20 and 28, and the claims that depend from them.

Conclusion

For at least the foregoing reasons, Applicant believes that each of the presently pending claims in this application is in immediate condition for allowance. Accordingly, Applicant respectfully requests a favorable action on the merits. If the Examiner has any further comments or suggestions, Applicant invites the Examiner to telephone the undersigned attorney to expedite the handling of this matter.

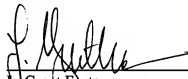
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arguments, representations, and/or amendments presented or contained in the present patent application are only applicable to the present patent application and should not be considered when evaluating any other patent or patent application.

The Commissioner is hereby authorized to charge any additional fees which may be required for this application, or credit any overpayment, to Deposit Account No. 08-2623. If any extensions of time are needed for timely acceptance of these documents, such an extension is hereby requested and payment of any such extension fees is authorized from Deposit Account No. 08-2623.

Respectfully submitted,

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